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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,559	08/15/2001	Glyn Dawson	ARCD:351US/GNS	9827

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Gina N. Shishima
FULBRIGHT & JAWORSKI L.L.P.
SUITE 2400
600 CONGRESS AVENUE
AUSTIN, TX 78701

EXAMINER	
AEDER, SEAN E	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/930,559	DAWSON ET AL.	
	Examiner	Art Unit	
	Sean E. Aeder, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-57 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-57 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

2

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, 8-12, 15-21, 24, 25, 27, 32-39, 42, 43, and 46 drawn to a method of inhibiting cancer comprising administering a composition comprising a PPT1 modulator comprising of a peptide that comprises at least or at most 5 contiguous amino acids from SEQ ID NO:3, classified in class 514, subclass 2.

II. Claims 1-6, 8-10, 13-21, 24, 26, 27, 32-37, 40-43, and 46 drawn to a method of inhibiting cancer comprising administering a composition comprising a PPT1 modulator comprising of a peptide that comprises at least or at most 5 contiguous amino acids from SEQ ID NO:4, classified in class 514, subclass 2.

III. Claims 1-6, 8-10, 15-23, 27 32-37, and 42-46 drawn to a method of inhibiting cancer comprising administering a composition comprising a PPT1 modulator comprising a peptide wherein the peptide is DAP1, classified in class 514, subclass 2.

IV. Claims 1-7, 28-30, 32, and 33 drawn to a method of inhibiting a cancer comprising administering a composition comprising a nucleic acid modulator of PPT1, classified in class 514, subclass 44.

V. Claims 1-4 and 31-33, drawn to drawn to a method of inhibiting cancer comprising administering a composition comprising an antibody that recognizes PPT1, classified in class 424, subclass 130.1+.

VI. Claims 47-53, drawn to a method of screening a candidate substance for anti-cancer activity, classified in class 435, subclass 4.

VII. Claims 54, drawn to a pharmaceutical composition comprising a recombinant vector containing a PPT1 gene segment positioned in the reverse orientation, classified in class 514, subclass 44.

VIII. Claims 55-56, drawn to a pharmaceutical composition comprising a peptide or peptide mimetic that selectively binds to PPT1 and that is covalently attached to a lipid component through a non-hydrolyzable linkage, classified in class 530, subclass 350+.

IX. Claim 57, drawn to a method for screening for cancer or pre-cancer, classified in class 424, subclass 9.1.

The inventions are distinct, each from the other because of the following reasons:

The inventions of groups I-VI and IX represent materially distinct methods. Group I is drawn to a method of administering a composition comprising at least 5 continuous amino acids from SEQ ID NO:3, group II is drawn to a method of administering a composition comprising at least 5 contiguous amino acids from SEQ ID NO:4, group III is drawn to a method of administering a composition comprising DAP1, group IV is drawn to a method of administering a composition comprising a nucleic acid modulator, group V is drawn to a method of administering a composition comprising an antibody, group VI is drawn to a method of screening a candidate substance for anti-cancer activity, and claim IX is drawn to a method for screening for cancer or pre-cancer. Each group differs in objectives, method steps, and chemically distinct reagents to accomplish the objectives. Searching all the groups with all the different objectives, method steps, and reagents would invoke a high burden of search.

The inventions of groups I-III represent chemically distinct methods comprised of a multitude of different amino acid sequences which are made by materially different methods and have different modes of operation, different functions and different effects. Further, although the groups are classified similarly, each search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. Currently, there are approximately eight different databases that

accompany the results of a search of one discrete amino acid or nucleotide sequence and each result set from a particular database must be carefully considered. Hence, the search of all such peptides in the databases would require extensive searching and review and would invoke a high burden of search.

The inventions of groups VII and VIII represent distinct products, as outlined in the instant specification. The invention of group VII is drawn to a recombinant vector containing a nucleotide sequence, while the invention of group VIII is drawn to a pharmaceutical composition comprising a peptide or peptide mimetic that is covalently attached to a lipid component. The nucleotide construct in group VII and the peptide/lipid composition in group VIII represent chemically distinct compounds. Searching and examining these compounds together would invoke a serious search burden on the examiner, as stated above.

Inventions VII and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the pharmaceutical composition comprising a recombinant vector containing a PPT1 gene segment positioned in the reverse orientation can be used to alter PPT1 expression for a method of screening.

Inventions VIII and I-III are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the pharmaceutical composition comprising a peptide or peptide mimetic that is covalently attached to a lipid component can be used to produce antibodies.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and

> Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**
>
> Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA

GARY NICKOL
PRIMARY EXAMINER